

10/018,616

- 4 -

A0000060-01-MG
(PC17929)REMARKS*Claim disposition*

Claims 1-2, and 4-10 are pending in the application.

New claim 11 is added.

Claims 1-2, and 4-11 will be pending in the application upon entry of this amendment

Withdrawal of the rejections under 35 U.S.C. § 102 (e), is respectfully requested

Claims 1-2, 6, and 9 were rejected under 35 U.S.C. § 102 (e), for anticipation by U.S. Patent 6,451,857 B1 (Hurtt *et al.*). The Office Action states that "Hurtt teaches a composition comprising two or more anti-epileptic compounds combined with one or more compounds selected from NSAID, analgesic, NMDA receptor antagonists, or combinations thereof, namely gabapentin/pregabalin/opioid, gabapentin/pregabalin/NSAID, gabapentin/pregabalin/naproxen (column 5, lines 38-49), that is useful for treating pain including inflammatory pain (column 5, 50-60 and column 6, lines 8-19) wherein said composition is prepared in unit dosage form (column 6, lines 20-45)".

Independent claim 1 has been amended to include the recitation "wherein said composition does not further contain an NSAID, analgesic, NMDA receptor antagonist or opioid". Independent claim 6 has been amended to include the recitation "wherein said method does not further comprise administering an NSAID, analgesic, NMDA receptor antagonist or opioid". Independent claim 7 has been amended to include the recitation "wherein said method does not further comprise concomitant administration of an NSAID, analgesic, NMDA receptor antagonist or opioid". Therefore, the compositions and methods referred to in Hurtt *et al.* are explicitly excluded from the present claims

Furthermore, as argued in Applicant's previous response, and in contrast to the present claims, the methods and compositions referred to by Hurtt *et al.* do not mention a synergistic effect. Accordingly, as Hurtt *et al.* do not teach every limitation of the present claims, Applicants submit that the claims are not anticipated by Hurtt *et al.* Therefore, Applicants respectfully request that this rejection under 35 U.S.C. § 102 (e), be withdrawn.

BEST AVAILABLE COPY

10/018,616

- 5 -

A0000060-01-MG
(PC17929)Withdrawal of the rejections under 35 U.S.C. § 103, is respectfully requested

Claims 4, 5, 8, and 10 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 6,451,857 B1 (*Hurtt et al.*). The Office Action indicates that the determination of the ratios or dosages of the claimed inventions under consideration are within the skill of the ordinary skilled artisan who "would be motivated to determine optimum amounts to get the maximum effect of the drug".

Applicant submits that it is well established that motivation to try, without more, is not the proper standard to establish a *prima facie* case of obviousness. Rather, while the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references; the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made and not in hindsight; and the prior art reference or combination of references must teach or suggest all the limitations of the claims. See *Karsten Mfg. Corp. v. Cleveland Gulf Co.*, 242 F.3d 1376, 1385, 58 U.S.P.Q.2d 1286, 1293 (Fed. Cir. 2001); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

As more fully stated above, independent claims 1, 6, and 7 have each been amended to explicitly exclude the methods and compositions referred to by *Hurtt et al.* That is, *Hurtt et al.* is deficient with respect to teaching or suggesting compositions comprising gabapentin and pregabalin in the absence of one or more compounds selected from the group consisting of NSAIDs, analgesics, NMDA receptor antagonists, or combinations thereof. Similarly, *Hurtt et al.* is deficient with respect to methods employing such compositions. Accordingly, Applicants submit that the *Hurtt et al.* reference does not contain the requisite motivation to modify the combinations referred to in *Hurtt et al.* to arrive at the claimed compositions methods of the present invention under consideration, let alone with a reasonable expectation of success.

Furthermore, as argued in Applicant's previous response, and in contrast to the present claims, the methods and compositions referred to by *Hurtt et al.* do not mention a synergistic effect. Accordingly, and further in view of the amendments submitted herein, Applicants submit that the *Hurtt et al.* reference does not contain the requisite motivation discussed above.

10/018,616

- 6 -

A0000060-01-MG
(PC17929)

Therefore, Applicants submit that the claims under consideration are not *prima facie* obvious over Hurt et al. and respectfully request that this rejection under 35 U.S.C. § 103, be withdrawn.

NEW CLAIM 11

New claim 11 recites "A pharmaceutical composition according to claim 1 wherein the ratio of gabapentin to pregabalin is at least 10:1 by weight". Support for this new claim is found throughout the specification and claims. For example, see claims 4, 5, and 10, as well as Figure 4. Applicants also respectfully note that Figure 4 clearly represents a synergistic effect (square symbols) in comparison to an additive effect (circles). Accordingly, Applicants submit that the present rejections should not be extended to new claim 11.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is respectfully solicited.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper to Deposit Account No: 23-0455.

In the event the Examiner wishes to discuss any matter concerning this application, he is welcomed to communicate with the undersigned by telephone.

Respectfully submitted,

Date: April 25, 2005

By: Mehdi Ganjeizadeh
Mehdi Ganjeizadeh
Registration No. 47,585
Warner-Lambert Company LLC
2800 Plymouth Road
Ann Arbor, MI 48105
Telephone: (734) 622-3831
Facsimile: (734) 622-2928